K121115

SECTION 5.0: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

JUN 29 2012

A. Submitter Information

Submitter's Name:	Ostial Corporation
Address:	510 Clyde Avenue Mountain View, CA 94043
Telephone:	650-903-9100 x 232
Fax:	650-903-9119
Contact Person:	Kaitlin von Hoffmann Clinical and Regulatory Associate
Date of Preparation:	April 17, 2012

B. Subject Device

Trade Name:	Flash PTA Balloon Dilatation Catheter
Common/Usual Name:	Balloon Catheter
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250, Product Code LIT)

C. Predicate Device Name(s)

Primary Predicate:

Trade Name(s):	Sterling PTA Balloon Dilation Catheter, K053118
Classification Name:	Catheter, Percutaneous (21 CFR 870.1250, Product Code DQY)

Secondary Predicate:

Trade Name(s):	Flash PTA Balloon Dilatation Catheter, K120738
Classification Name:	Catheter, Angioplasty, Peripheral, Transluminal (21 CFR 870.1250, Product Code LIT)

D. Device Description:

The Flash PTA Balloon Dilatation Catheter is designed for dilation of stenotic ostial lesions in the peripheral vasculature. The Flash PTA Balloon Dilatation Catheter is a .014" guidewire-compatible, rapid exchange (RX) angioplasty balloon catheter with proximal anchoring and a working length of 135cm. The Flash PTA Balloon Dilatation Catheter uses a dual balloon design that features a compliant anchoring balloon, which prevents distal migration of the balloon during angioplasty. The second semi-compliant higher-pressure balloon allows for luminal dilatation of *de novo* lesions and post deployment stent expansion.

E. Intended Use:

The Flash PTA Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This device is also indicated for post-dilatation of balloon expandable stents in the peripheral vasculature.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

The purpose of this Traditional 510(k) is to seek an expanded indication for two of the Flash PTA Balloon Dilatation Catheter models cleared by 510(k) #K120738 on April 3, 2012.

In accordance with the current thinking of the FDA as reflected by The 510k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Draft Guidance dated December 27, 2011, Ostial Corporation is claiming two predicates for the subject device. The expanded indication for the

subject Flash PTA Balloon Dilatation Catheter is consistent with the overall intended use of the predicate devices, namely balloon dilatation within the peripheral vasculature.

The predicate Flash PTA Balloon Dilatation Catheter was cleared with an indication that is a subset of the proposed expanded indication. The expanded indication adds that the device is also indicated for post-dilatation of balloon expandable stents in the peripheral vasculature. The predicate and subject Flash PTA Balloon Dilatation Catheters are the exact same device. No design modifications or changes to packaging, manufacturing or sterilization have been made since the clearance of the predicate Flash device.

Additionally, substantial equivalence was established between the first iteration of the Flash PTA Balloon Dilatation Catheter and the primary predicate Sterling PTA Balloon Dilatation Catheter via the original Traditional 510(k) for the device product line, #K102482 dated February 25, 2011. The Sterling PTA Balloon Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, ilio-femoral, popliteal, renal and carotid arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. With respect to the subject device, the Sterling catheter features an equivalent design, packaging, fundamental technology, manufacturing and sterilization. The scope of the subject device's indication for use is narrower than that of the Sterling catheter, and both are indicated for post-dilatation of balloon expandable stents.

The subject device and predicate devices are substantially equivalent in terms of intended use, fundamental scientific technology, target population, and operating principles.

G. Performance Data:

Biocompatibility testing has previously been completed on the Flash PTA Balloon Dilatation Catheter. Requirements for biological evaluation of the proposed device were based on the Blue Book Memorandum issued on May 1, 1995, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices, Part 1:Evaluation and Testing." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed:

- ISO MEM Elution Assay
- ASTM Hemolysis Assay
- Complement Activation C3a and SC5b-9 Assay
- Thromboresistance Evaluation
- Materials Mediated Rabbit Pyrogen
- ISO Guinea Pig Maximization Sensitization
- ISO Acute Systemic Injection Test
- ISO Intracutaneous Reactivity Test
- Pyrogen (LAL) Chromogenic

The Flash PTA Balloon Dilatation Catheter was evaluated using the following in-vitro performance bench testing to confirm the performance characteristics as compared to the predicate device:

- Balloon Crossing Profile
- Catheter Shaft Diameter
- Angioplasty Balloon Rated Burst Pressure
- Anchoring Balloon Burst Volume
- Angioplasty Balloon Compliance
- Balloon Inflation Time
- Balloon Deflation Time
- Angioplasty Balloon Rated Burst Pressure (in Stent)
- Anchoring Balloon Burst Volume (in Stent)
- Angioplasty Balloon Fatigue
- Anchoring Balloon Fatigue
- Catheter Bond Strength
- Catheter Tip Pull Strength
- Catheter Torque Strength
- Simulated Use/Flexibility/Kink
- Radiopacity
- Angioplasty Balloon Fatigue (in Stent)
- Anchoring Balloon Fatigue (in Stent)

All test results demonstrate that the device materials, the manufacturing process, and the design for the Flash PTA Balloon Dilatation Catheter met the established specifications necessary for consistent performance according to its intended use.

H. Conclusions:

The Flash PTA Balloon Dilatation Catheter met all predetermined acceptance criteria of design verification and validation as specified by applicable standards, test protocols, and/or customer inputs. The Flash PTA Balloon Dilatation Catheter is substantially equivalent to the legally marketed predicate devices and does not raise any new safety or effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 29 2012

Ostial Corporation
c/o Kaitlin von Hoffmann
Clinical and Regulatory Associate
510 Clyde Avenue
Mountain View, CA 94043

Re: K121175
Trade/Device Name: Flash PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: April 17, 2012
Received: April 18, 2012

Dear Ms. von Hoffmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4.0: INDICATIONS FOR USE STATEMENT

510(k) Number: K121175

Device Name: Flash PTA Balloon Dilatation Catheter

Indication For Use: The Flash PTA Balloon Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature at aorto-ostial locations, including iliac, renal and carotid arteries. This device is also indicated for post-dilatation of balloon expandable stents in the peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M J Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121175